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This Report CONTAINS Confidential Business Information

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)  
U.S. Environmental Protection Agency  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

SUBJECT: TSCA 8(e)SUBMISSION

Dear Sir or Madam:

( ) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , an experimental pyrethroid insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is

has imported for R&D on behalf of (“ ”).

The following reports concerning have been submitted to your agency: Two acute oral toxicity studies with rats (November 15, 2007: 8EHQ-07-16995 & 16996); a preliminary development toxicology study with rats (January 7, 2008: 8EHQ-08-17027); a micronucleus study with rats (February 19, 2008: 8EHQ-08-17081); an acute inhalation toxicity study in rats (July 11, 2007: 8EHQ-08-17209); a two week oral toxicity study in dogs (October 9, 2008: 8EHQ-08-17297); a micronucleus study with rats (February 16, 2010: 8EHQ-10-17866); an in-vivo unscheduled DNA synthesis (UDS) assay in rat hepatocytes (April 5, 2010: 8EHQ-10-17907); effects on pre- and postnatal development, including maternal function in rats (May 21, 2010: 8EHQ-10-17958); an in-vivo unscheduled DNA synthesis (UDS) assay in female rat hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); and a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166).



Company Sanitized

recently learned of new toxicological effects in a fertility and embryonic development study in rats. An outline of the study follows:

Fertility and early embryonic development to implantation of \_\_\_\_\_ administered orally to rats

was administered orally by gavage to Crl:CD(SD) rats (20 animals/sex/group) at dose levels of 10, 40, and 150 mg/kg. Clinical observations noted tremor, salivation, stains around mouth and abdomen in male and female animals in the 150 mg/kg group. The NOEL was established for male and female animals at 40 mg/kg. Since the dosing period in the oral study was less than three months and the NOEL below 100 mg/kg; the NOEL below 200 mg/kg in an oral study of less than four weeks; and the occurrence of neurotoxic signs, \_\_\_\_\_ believes that the results are reportable under TSCA 8(e).

Performing Laboratory:

Environmental Health Science Laboratory

Study methods for study # 4211:

Animals: Crl:CD(SD) rats, males and females, 20 rats/sex/group

Age of animals at start of study: 10 weeks of age for male and female

Body weight range at start of study: 372-428g (for male), 211-244g (for female)

Administration route: oral by gavage

Dose levels: 10, 40, and 150 mg/kg

Treatment period: males for 32 days. Females for 23-29 days (from 15 days before mating to day 7 of gestation)

Observation items: Clinical signs

Results:

Mortality: One female of the 150 mg/kg group died.

Clinical signs: tremor, salivation, stains around mouth and abdomen in males and females in the 150 mg/kg group; clonic convulsion and lower body weight gain were observed in female animals at 150 mg/kg group. No treatment related effects in food consumption, necropsy, reproductive performance and early embryonic development were noted in all dose groups.

Substantiation of CBI Claims

We wish to substantiate \_\_\_\_\_'s claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, \_\_\_\_\_ wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm \_\_\_\_\_'s efforts to commercialize this compound. Please refer to the attached letter of March 17, 2010 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( \_\_\_\_\_ ).

Yours sincerely,

Technical Consultant

Encl.

cc: